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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,941	08/09/2001	John R. Stuelpnagel	A-67616-4/RMS/DCF/SRN	6890

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/18/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,941

Applicant(s)

STUELPNAGEL ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

FIRST ACTION ON THE MERITS

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The Provisional Application filed 9 February 1999 upon which priority is claimed does not provide adequate support under 35 U.S.C. 112 for claims 1-4 of this application because the provisional application does not teach or describe the instantly claimed "mapping a grid". The provisional application teaches incorporating fiducials into the assay structure to control alignment of the structure (page 22, lines 4-10) wherein the fiducials define an edge, stripe or have an orientation which allows translation of the images detected (page 23, lines 10-17). And the provisional application describes a fiducial template which is created from various images of the array (page 23, lines 18-32). But the provisional application does not teach or describe the instantly claimed mapping a grid.

Provisional Application filed 9 February 1999 upon which priority is claimed does not provide adequate support under 35 U.S.C. 112 for claims 5-10 of this application because the provisional application does not teach or describe the instantly claimed "determining the similarity of a first signal form at least one discrete site to at least one reference signal" (Claim 5) and "comparing said first signal to a threshold similarity measure obtained by comparing a reference signal to a theoretical signal" (Claims 6-10).

As such, the effective filing date for instant claims 1-10 is the filing date of parent application 09500,555 i.e. 9 February 2000.

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Specification

2. The disclosure is objected to because of the following informalities:

The first paragraph of the specification incorrectly identifies the instant application as a continuing application of 09/636,387 and 09/500,555. This cross reference is incorrect because the instant application is a continuation-in-part of 09/636,387.

Appropriate correction is required.

Claim Objections

3. Claims 3-4 are objected to because of the following informalities:

The claims incorrectly depend from Claim 38. The instant application does not contain a claim 38. For purposes of examination, Claims 3-4 are interpreted as depending from Claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 10 is indefinite for the recitation "said threshold similarity measure" because the recitation lacks proper antecedent basis in Claim 5. It is suggested that Claim 10 be amended to provide proper antecedent basis.

b. Claim 10 is further indefinite for the recitation "said first discrete site" because the recitation lacks proper antecedent basis in Claim 5. It is suggested that Claim 10 be amended to provide proper antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998).

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Regarding Claim 1, Walt et al disclose a method of determining the presence of a target analyte in a sample comprising acquiring a first data image (i.e. optical signature) of a random array composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent wherein said microspheres are distributed on said surface such that each of said discrete sites contain no more than one microsphere (Column 3, lines 35-45; Column 5, line 61-Column 6, line 29; and Fig. 5 & 7) mapping a grid (i.e. matrices) onto said first data image to create a registered first data image (i.e. optical signature) contacting said random array with a sample, acquiring a second data image from said array with said sample, mapping a grid (matrices) onto said second data image to create a registered second data image and comparing first and second registered data image to determine the presence or absence of said target analyte (Column 18, line 59-Column 19, line 53; Column 27, lines 30-50; and Fig. 10).

Regarding Claim 2, Walt et al disclose the method wherein said discrete sites are wells (Column 6, lines 22-29).

Regarding Claim 3, Walt et al disclose the method wherein said bioactive agents are proteins (Column 8, lines 50-59).

Regarding Claim 4, Walt et al disclose the method wherein said bioactive agents are nucleic acids (Column 9, lines 41-50).

Regarding Claim 5, Walt et al disclose a signal preprocessing comprising acquiring a first data image (i.e. optical signature) of a random array composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent wherein said microspheres are distributed on said surface such that each of said discrete sites contain microspheres (Column 3, lines 35-45; Column 5, line 61-Column 6, line 29; and Fig. 5 & 7) determining the similarity of a first signal from at least one discrete site to at least one reference signal wherein

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when said first signal is similar to at least one of said reference signals, said discrete site contains a bead (Column 19, lines 31-53).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998) in view of Lockhart et al (U.S. Patent No. 6,040,138, filed 15 September 1995).

Regarding Claims 6-10, Walt et al teach a signal preprocessing comprising acquiring a first data image (i.e. optical signature) of a random array composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent wherein said microspheres are distributed on said surface such that each of said discrete sites contain microspheres (Column 3, lines 35-45; Column 5, line 61-Column 6, line 29; and Fig. 5 & 7) determining the similarity of a first signal from at least one discrete site to at least one reference signal wherein when said first signal is similar to at least one of said reference signals, said discrete site contains a bead (Column 19, lines 31-53). Walt et al compare a first signal and second signal to determine bead presence (Column 19, lines 46-53) which clearly suggests that they compare the signal to a threshold signal (e.g. first signal) to determine presence of the bead.

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Additionally, signal detection and comparison to a threshold measure was well known in the art at the time the claimed invention was made as taught by Lockhart et al who teach a similar method of signal processing. The method of Lockhart et al comprises acquiring a first data image of the array (i.e. signal intensities of the control sample on the array) wherein the array comprises a substrate with a surface comprising discrete sites bioactive agent and obtaining a first signal from a discrete site and comparing the signal to a threshold measure (threshold intensity value) to thereby determine the presence of a bioactive agent at the site (Column 23, line 41-Column 24, line 6) whereby a true signal is distinguished from a background signal. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the threshold measure of Lockhart et al to the signal detection and comparison of Walt et al to thereby determine presence or absence of a bead, to discard a signal below the threshold and to accurately analyze and distinguish signals from background signals as taught by Lockhart et al (Column 23, line 41-Column 24, line 6).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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11. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49, 53 and 54 of copending Application No. 09/636,387 in view of Walt et al (U.S. Patent No. 6,327,410). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of determining the presence of a target analyte comprising acquiring a data image and differ only in the instant claims are drawn to mapping a grid onto the data image to create a registered data image. However, grid mapping (i.e. matrices) to provide a registered data image (optical signature) was well known in the art at the time the claimed invention was made as taught by Walt et al who teach that matrices-forming optical signatures facilitate comparison of optical signature and analyte detection (Column 19, lines 31-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the '387 method by mapping a grid onto the data image to create the registered data image for the expected benefit of facilitating analyte detection as suggested by Walt et al (Column 19, lines 47-53).

12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this


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application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
March 12, 2003